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Citation for final published version:

Maillard, Jean-Yves ORCID: <https://orcid.org/0000-0002-8617-9288> 2018. Are amine-only-containing products sporicidal? Journal of Hospital Infection 99 (1), pp. 115-116. 10.1016/j.jhin.2018.02.002 file

Publishers page: <http://dx.doi.org/10.1016/j.jhin.2018.02.002>
<<http://dx.doi.org/10.1016/j.jhin.2018.02.002>>

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Are amine only-containing products sporicidal?

Sir,

Clostridium difficile infection is linked to significant morbidity and mortality. *C. difficile* (endo)spores can survive on surfaces in healthcare settings for long period of time, which makes the elimination of these spores from surfaces important. Bacterial spores are notoriously resistant to chemical and physical processes [1,2] and not surprisingly they are used as biological indicators for many sterilization processes. Their resistance is intrinsic and linked to their structure, dehydration and the presence of small acid soluble proteins in their core protecting them from external chemical and physical damage [2]. When compared to other microorganisms, bacterial endospores are among the most resistant “microorganisms” to disinfection [3]. Our understanding of sporicides have not really changed since the 1990 [4] with the excellent review by Russell, although biocidal products have become more complex in their composition. Literally a “sporicide” is a biocide/product that can kill spores and we need to reflect on the distinction between this definition and the requirement from the regulator for manufacturers’ to make a sporicidal claim on label. In the literal sense, killing one spore would satisfy the definition of a sporicide. In reality, for a sporicidal product, the destruction of 10^3 spores is required under defined conditions [5]. There is no approved European standard sporicidal test for *C. difficile*, although a UK-derived sporicidal *C. difficile* test has been proposed [6], for which a 10^5 reduction in spores is required. These efficacy tests rely on an efficient and demonstrable neutralisation protocol, and failure to quench the active(s) can lead to a misinterpretation of a “sporicidal” activity [7]. Unfortunately, a misinterpretation of the neutralisation validation test results when following a standard protocol, can also lead to erroneous sporicidal claim [8]. Complex formulations, notably where several amine-based biocides are used, can be difficult to neutralised. Our current understanding of sporicides, in the sense that a sporicide should kill 10^3 - 10^6 spores, has not really changed over the years, and only a few biocides have been shown to have a sporicidal activity [1,4,7]; amine-based products are, to date, not among these [4,8,9]. It is thus puzzling and possibly concerning that products containing solely amines are being used as sporicides in healthcare settings.

Conflict of interest statement

None

Funding source

None

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